REMARKS

Claims 76-110 are pending in the present application. With the present amendment, claim 107 is canceled and claims 76, 81, 101, 103, and 104 are amended. Support for the claim amendments can be found throughout the specification and claims as filed. Claim amendments are for the purpose of improved clarity unless otherwise noted. Applicants reserve the right to pursue the claims, as filed, in continuing applications.

Rejection under 35 U.S.C. § 112, definiteness

Claims 76-87, 90-93, 96-98, and 100-110 are rejected under 35 U.S.C. § 112 as allegedly indefinite for recitation of the term indazole. Although Applicants do not necessarily agree, Applicants have amended the claims to include the indazole structure. Applicants respectfully request that the rejection be withdrawn.

Rejection under 35 U.S.C. § 112, first paragraph

Claims 76-87, 90-93, 96-98, and 100-110 are rejected under 35 U.S.C. § 112, first paragraph, as allegedly nonenabled. To the extent the rejection applies to the claims, as amended, Applicants respectfully request reconsideration of the rejection because there is no evidence of record suggesting that a skilled practitioner would be unable to make and use the claimed compositions.

The initial burden to support an enablement rejection rests on the Examiner. In this regard, § 2164.04 of the MPEP states: "the examiner has the initial burden to establish a reasonable basis to question the enablement provided for the claimed invention. *In re Wright*, 999 F.2d 1557, 1562, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993)(examiner must provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure)." MPEP § 2164.04 further states that a specification **must** be taken as being in compliance with the enablement requirement of 35 U.S.C. § 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support. *In re Marzocchi*, 439 F.2d 220, 224, 169 USPQ 367, 370 (CCPA 1971)." The MPEP quotes *Marzocchi* as follows:

> it is incumbent upon the Patent Office, whenever a rejection on this basis is made, to explain why it doubts the truth or accuracy of any statement in a

> supporting disclosure and to back up assertions of its own with acceptable evidence or reasoning which is inconsistent with the contested statement. Otherwise, there would be no need for the applicant to go to the trouble and expense of supporting his presumptively accurate disclosure.

439 F.2d at 224, 169 USPQ at 370.

The present rejection does not satisfy the *Marzocchi* standard. Although the Office Action provides a lengthy analysis of certain factors to be considered in assessing whether undue experimentation would be required, close inspection not only reveals that these factors do not support rejection of the present claims but, in fact, indicate that any experimentation associated with the practice of the claimed inventions would be routine in nature and well within the level of skill in the art.

BREADTH OF THE CLAIMS

Although the Office Action makes bare assertions that the claims are broad in scope, it fails to provide evidence that their breadth is beyond the level of skill in the art. As noted in the specification, those skilled in the art were quite familiar with using metallopharmaceuticals for cancer therapy. For example, radionuclide labeled monoclonal antibodies, antibody fragments and other proteins or polypeptides that bind to tumor cell surface receptors are known for use in cancer imaging and treatment. Those skilled in the art are also familiar with the use of small molecules such as peptides, that bind to tumor cell surface receptors. For example, an In-111 labeled somatostatin receptor binding peptide, In-111-DTPA-D-Phe^1-octeotide, is in clinical use in many countries for imaging tumors that express the somatostatin receptor (Baker, et al. Life Sci., 1991, 49, 1583-91 and Krenning, et al., Eur. J. Nucl. Med., 1993, 20, 716-31). Given this familiarity there is no reason to believe that a skilled practitioner would be unable to synthesize a composition of the present invention and use it as a diagnostic or therapeutic.

2. THE PRESENCE OR ABSENCE OF WORKING EXAMPLES

The Office Action also fails to provide any evidence that the number of working examples provided in the specification would be insufficient for those skilled in the art to practice the claimed inventions. Although the Office Action notes that the specification does

not include examples documenting synthesis and use of all possible compositions, such examples are not required as a condition for patentability. In fact, it is well-established that an applicant need not include *any* working examples demonstrating a claimed invention. I*n re Fouche*, 169 U.S.P.Q. 429, 434 (C.C.P.A. 1971). Notably, the specification provides Examples 1-58 on pages 115-250 which provide representative compounds of the present invention. Thus, Applicants' provision of representative examples falls far short of demonstrating any lack of enablement.

3. THE STATE OF THE PRIOR ART

The claims, as amended, recite specific indazole nonpeptides for use in the present invention. The Action provides no reason to believe that a skilled practitioner would have any difficulty determining whether a selected indazole nonpeptide binds to a receptor that is upregulated during angiogenesis.

4. PREDICTABILITY OF THE ART

The Office Action fails to provide any evidence demonstrating any unpredictability as to whether the claimed compositions will demonstrate some measurable level of activity. For example, it is well known that radiopharmaceuticals are useful for both diagnostics and therapeutics for treating cancer.

5. AMOUNT OF GUIDANCE PRESENTED/ QUANTITY OF EXPERIMENTATION

Here, too, the Office Action presents a bare allegation without any supporting evidence. Although the Office Action appears to suggest that Applicants should have presented more working examples, the question that remains unanswered is "why?". Absent some evidence indicating that those skilled in the art having read Applicants' specification would not be able to practice the claimed inventions, there is no reason to believe that the guidance provided in the specification is insufficient within the meaning of §112.

6. THE NATURE OF THE INVENTION

Again, the Office Action fails to provide any evidence that the nature of Applicants' inventions is such that they could not be practiced by those skilled in the art.

Thus, as is evident from the foregoing analysis, the Office Action's unsupported contentions as to alleged difficulties that those skilled in the art would encounter in practicing the claimed inventions simply do not constitute evidence or technical reasoning of the sort required to substantiate allegations that there is a lack of enablement. In summary, Applicants submit that the Action has mischaracterized the relative skill of those in the art of metallopharmaceutical chemistry and has improperly rejected the claims as non-enabled. Accordingly, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 112, first paragraph, be withdrawn.

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